29th LRP Panel Meeting on July 21, 2017

Members experience registration timeline
New registration 9-12 months (of course, some members experience even quicker but 9-12 months is the average)
Minor change 1 month
Major change 3-6 months

New medical device regulation implementation status

- Exploring idea of implement registration part first while settling the user control part
- LRP Panel believe it takes 2-3 years (the quickest) to roll out the regulation and there will be grace period

Tips to make listing and review more efficient

- Provide video for device or therapy education in dossier especially the technology is very new
- There could be many product codes in the application, it will be helpful to provide detail description and use of each product code
- If different product code/serial number or even different product name is used in HK (compared to source country), please provide DoC (Declaration of Conformity) to explain the difference will do
- For UDI, MDCO is in observation stage to see what is the harmonized approach
- For product change, it will be helpful to include change history, rationale of change, comparison table of old and new change

Next steps

- The team agreed that it will be helpful to draft a guidance document on product change. LRP Panel will form a task force to focus on top 10 changes and suggested documentation required before next forum
- Next forum is 17 Nov. MDCO will consider to bring staff to attend